OCT 2 6 2001

510K SUMMARY

K013348

Submitted By:	ERBE USA, Inc. 2275 Northwest Parkway Suite 105 Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal
Date Prepared:	10/05/01
Common Name:	Argon Plasma Coagulator (APC) Connector Hose and Probes
Trade/Proprietary Name:	ERBE APC Handle and Applicators
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)
Product Code:	79GEI
Legally Marketed Device:	Accessories (APC Connector Hose and Probes) submitted in the ERBE APC 300 Argon Plasma Coagulator and Accessories, 510(k) Number: K963189

Note: The APC Connector Hose and Probes being submitted in this premarket notification are modified from the accessories in the above 510(k). The modifications were determined to require a 510(k) submission.

Device Description:

The APC Connector Hose is a flexible connecting cable. It has a pronged connecting end to the APC Probe and is 8.2ft. (2.5m) in length (Note: The other end of the hose connects to an ERBE Argon Plasma Coagulator Model APC 300.). The connector ends of the Hose are made of polyamide, poly ether ether ketone (PEEK), and plastic (Thermoflex). The cable portion of the Hose is silicone. The Hose is a conduit for both electrosurgical current and argon gas. The APC Connector Hose is provided non-sterile and is reusable (Note: The cleaning and sterilization processes have been validated and are provided in the Notes for use to the customer.).

The APC Probes are also tubular instruments and are flexible. They are provided in various lengths and diameter sizes to accommodate the various size/types of endoscopes for a variety of applications (i.e., the treatment of various target tissues inside a patient). The lengths of the APC Probes are 4.9ft. (1.5m) to 9.8ft. (3m). The diameters of the APC Probes are 4.5 French (1.5mm) to 9.6 French (3.2mm). For the Probe, the connector end is made of plastics (polypropylene and Thermoflex). The tube portion of the Probe is made of Teflon (PTFE) and has a stainless steel wafer shape electrode close to the tip for terminating electrical current. For the lateral opening (side fire) Probe there is a glued on ceramic tip. The APC Probes have either an axial (straight fire) or a lateral (side fire) opening allowing the energy to be delivered straight or at a 45 to 90 degree angle. The two types of openings for the APC Probes allow the physician a choice in the direction of delivering the argon plasma to the treatment site. The APC Probes are provided sterile by means of ethylene oxide and are disposable (Single Use) [Note: The sterilization cycle has been validated. See Section IV, Sterilization Information, IV-1 to IV-2).

The APC Connector Hose and Probes are accessories of the ERBE Argon Plasma Coagulator Model APC 300 (Note: The Coagulator is used with an ERBOTOM ICC Series Electrosurgical Generator Unit.). The APC Connector Hose attaches to gas as well as electrical inputs of the Coagulator and then to an APC Probe (Note: The Coagulator has an instrument recognition system which identifies the Probe for argon gas flow purposes.). An endoscope is manipulated inside the patient to locate tissue that requires treatment. Upon finding the target tissue, the APC Probe is threaded into the working channel of the endoscope, until the tip of the APC Probe slightly protrudes from the end of the scope. Then opening of the APC Probe is positioned towards/in close proximity of the area to be treated ((Note: The APC Probes have depth marker rings close to the tip for positioning purposes.). The APC/ICC system is activated via a footswitch. When high frequency voltage reaches the critical level and the proximity to tissue is close enough, electrically conductive argon plasma forms in the gas stream. This allows the current to flow between the probe and the tissue. Current density upon arrival at the tissue surface causes coagulation. The application of the energy to the tissue is uniform and contact free.

Intended Use:

The APC Connector Hose and Probes are intended for use in argon plasma coagulation. The device is used to treat many conditions in endoscopy for various surgical procedures.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

APC Connector Hose

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Similarities
The modified Hose has the same performance specifications, intended use, packaging, and labeling. Also like the predicate, it is provided non-sterile and is re-usable with the same cleaning procedures.

Differences
For the modified Hose, the end that connects to the APC Filter/Coagulator (Model APC-300) has a slightly smaller insert thread diameter (Note: Change is from 7.2mm to 6.8mm) in comparison to the predicate. This change was made to make the connection to the APC Filter/Coagulator (Model APC-300) more secure/tighter. Also, the modified Hose has a one piece y-connector where as the predicate's is a two-piece v-connector (Note: Change enhances integrity). The cable of the modified Hose is more flexible then the cable of the predicate, making manipulation easier. In addition, the connector end of the Hose that attaches to an APC Probe is made of a material (i.e., a plastic in comparison to a polyamide) that is harder and has two pins instead of one in comparison to the predicate (Note: The modified connection to the APC Probe is more secure.).

All the changes have been verified or validated in design control.

Finally, a contract manufacturer will make the modified APC Connector Hose in comparison to the predicate that is made in-house by ERBE Elektromedizin GmbH.

APC Probe

Similarities
The modified APC Probes have the same performance specifications, intended use, and labeling. Dimensional and packaging specifications are very similar. Also like the predicate, it is provided sterile by ethylene oxide and is single use.

Differences
For the modified APC Probes, the end that joins to the APC Connector Hose has a receptacle for a two-prong attachment instead of one pin. Also the material of the connector end is made of a plastic instead of nylon. The attachment end is hardier and the connection to the APC Connector Hose is more secure with the two pins. One of the APC Probes (P/N: 20132-100) is slightly longer than the longest predicate (P/N: 20132-166) [Note: Increase is from 2.5m/8.2ft. to 3m/9.8ft.] The 3m/9.8ft. Probe is for use in an endoscope that has a longer channel. Also, the internal electrode that is close to the tip was modified from a coiled wire to a solid wafer shaped plate. The electrode ignites better and cools quicker because of the larger surface area in the modified APC Probe (i.e., there is more consistency in activation). In addition, the ceramic tip has been found not to be necessary for the straight fire Probes which helps reduce agglutination at the tip.

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The packaging specifications have slightly changed from the predicate device submitted in the 510(k). The package is shorter and wider (260 x 230mm in comparison to 400 x 205mm).

All the changes have been verified or validated in design control.

Finally, a contract manufacturer will manufacture the modified APC Probes in contrast with the predicate devices, which are made in-house by ERBE Elektromedizin GmbH.

Conclusion:

The APC Connector Hose and Probes have the same intended use, principles of operation, and technological characteristics as the accessories in the previously cleared predicate device.

The dimensional or structural modification as well as the material change to the connector ends of the APC Connector Hose does not adversely affect the safety or effectiveness of the accessory. Also, the contract manufacturing of the APC Connector Hose does not raise safety or efficacy concerns.

The structural modification to the connector end of the APC Probes, the material changes in the APC Probes, as well as the redesigned internal electrode does not adversely affect the safety or effectiveness of the accessories. Also, the one Probe being longer and the packaging changes did not have a safety or efficacy impact. In addition, the contract manufacturing of the APC Probes does not raise safety or efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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OCT 2 6 2001

Mr. John Tartal
Quality Assurance/Regulatory Affairs
Manager
ERBE USA, Inc.
2275 Northwest Parkway, Suite 105
Marietta, Georgia 30067

Re: K013348
Trade/Device Name: ERBE APC Handle and Applicators
Regulation Number: 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: October 5, 2001
Received: October 9, 2001

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013348

DEVICE NAME: APC Connector Hose and Probes

INDICATIONS FOR USE:

APC Coagulation

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER P. IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter-
(Optional Forma

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013348